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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,654	08/20/2003	Ihor Shevchuk	6750-130-999	8830

20583 7590 10/04/2006

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222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,654	SHEVCHUK ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 4/21/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS filed 04/21/2004.

Claims 1-35 are pending and included in the prosecution.

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,149,538 ('538).

US '538 teaches transdermal delivery patch form comprising opioid analgesics and one or more antagonists for said opioid in an effective amount to attenuate the euphoric effect of said opioid if the patch is tampered with (abstract; col.3, lines 42-43). The preferred opioid is buprenorphine and the preferred antagonist is naltrexone (col.2, lines 65-68). Opioid analgesics include buprenorphine, fentanyl, oxycodone, and pharmaceutically acceptable salts thereof (col.4, lines 31-52). The patch comprises one or more antagonists including naltrexone, naloxone, nalmefene, cyclazocine, pharmaceutically acceptable salts thereof, and mixtures thereof (col.5, lines 26-39). The patch is reservoir or matrix type, gel, cream or paste (col.4, lines 10-11, 63-64).

US '538 does not explicitly teach the presence of the free base antagonist and its salt in the patch and their amounts and ratios. The reference does not teach a kit comprising the transdermal patch and printed instruction on how to use the kit.

US '538 suggests combination of one or more opioid analgesics and combination of one ore more antagonists including the antagonist, i.e. free base, and their salts. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute

predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide transdermal patch comprising opioid analgesic and antagonist in the free base or salt form as disclosed by US '538, and use both the free base and salt of the antagonist motivated by the knowledge available to the skilled artisan that salts and free bases of the drugs have different solubility and bioavailability and combination of both will provide different release time providing prolonged period of release instead of having the antagonist in one form that has the same release period, with reasonable expectation of having the transdermal patch comprising opioid analgesic and antagonist in the free base and in the salt form to provide prolonged release of the antagonist all through the use time of the device.

Regarding the claimed amounts and ratios, the references do not specifically teach the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention. One having ordinary skill in the art would have determined the amount of the opioid and its antagonist according to specific

patient need and severity of pain. One having ordinary skill in the art would have adjusted the ratio between the salt and free base of the antagonist according to their solubility and bioavailability of the salt and free base of each antagonist to obtain continuous antagonistic effect as well as effective pain relieve.

Regarding printed instruction, it is a routine work for all the available pharmaceuticals and cosmetics, and one having ordinary skill in the art would always includes a printed instruction with any pharmaceutical product to ensure effective non-hazardous use of the pharmaceuticals.

Therefore, the invention as whole is *prima facie* obvious in view of US '538.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis Ghali
Examiner
Art Unit 1615

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